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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,551	12/08/2003	Todd K. Whitehurst	AB-308U	4571
23845	7590	10/24/2005	EXAMINER	
ADVANCED BIONICS CORPORATION 25129 RYE CANYON ROAD VALENCIA, CA 91355			GREENE, DANA D	
		ART UNIT		PAPER NUMBER
				3762

DATE MAILED: 10/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/731,551	WHITEHURST ET AL.	
	Examiner	Art Unit	
	Dana D. Greene	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 July 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-28 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 08 December 2003 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date: _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The examiner has given full consideration to Applicant's response filed on July 27, 2005. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

Claim Objections

Claim 21 is objected to because of the following informalities: The word "patent" in line 1 should be "patient." Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-28 stand rejected under 35 U.S.C. §102(e) as being anticipated by Zabara et al. (US 6,721,603 B2, hereinafter "Zabara"). With reference to claims 1 and 18, Zabara is considered to disclose:

providing a miniature leadless implantable stimulator with at least one electrode and with a size and shape suitable for placement of the entire stimulator adjacent to a nerve (see col. 4, ln. 24-28, Zabara). The disclosed medical interventional device is considered to anticipate the claimed stimulator

because both are implanted in a patient in a minimally invasive way to access a designated nerve to effect electrical stimulation;

implanting the stimulator adjacent to at least one tissue influencing the angina pectoris of the patient, which tissue is at least one of an intercostal nerve and an intercostal nerve branch (see col. 3, ln. 40-50 and col. 11, ln. 5-15, Zabara). The disclosed therapy for alleviating chronic pain is considered to anticipate the claimed method of influencing the angina pectoris of the patient because both work to alleviate pain by electrical stimulation of any one or more, or all, of the afferent fibers of the sympathetic and thoracic spinal nerves;

providing operating power to the stimulator; using an external appliance to transmit stimulation parameters to the stimulator; receiving the stimulation parameters at the stimulator; and generating stimulation pulses in accordance with the stimulation parameters, which pulses are generated by the stimulator (see col. 13, ln. 50 - col. 14, ln. 5, Zabara). The disclosed method of using the stimulus generator is considered to anticipate the claimed method of providing operating power because both provide stimulation signal parameters to designate the frequency with which a stimulation signal is applied to the electrode;

delivering stimulation pulses via the stimulator to the at least one of the intercostal nerves and intercostal nerve branches influencing angina pectoris as a treatment for angina pectoris (see col. 3, ln. 8-13, Zabara). The disclosed implantation in the spinal cord to suppress pain is considered to anticipate the claimed method of delivering stimulation pulses because both alleviate chronic

pain, by electrical stimulation of the afferent fibers of the specific nerve. The disclosed invention clearly anticipates the current claims because both provide therapy to alleviate chronic pain (angina pectoris, ischemia, etc.) by electrical stimulation of thoracic spinal nerves, which include the intercostal nerves.

Referring to claims 4-8 and 13-17, Zabara is considered to disclose at least one sensor and the method further comprises sensing at least one condition of the patient (see col. 4, ln. 48-51 and col. 13, ln. 50-65, Zabara). The disclosed sensor is considered to anticipate the claimed because both detect the manifestation of the pain and emit an activating signal to trigger activation of the implanted device.

Referring to claim 9, Zabara is considered to disclose:

providing a miniature implantable stimulator with at least one electrode and with a size and shape suitable for placement of the at least one electrode adjacent to a nerve (see col. 4, ln. 24-37, Zabara). The disclosed method is considered to anticipate the claimed method because both provide an electrode to be implanted in stimulating and sensing relation on to the designated nerve;

implanting the at least one electrode near at least one tissue influencing the angina pectoris of the patient, which tissue is at least one of an intercostal nerve and an intercostal nerve branch (see col. 12, ln. 50-63, Zabara). Zabara anticipates the claimed invention because both disclose a method of implanting electrodes on nerves to receive a stimulation signal to treat pain. The nerves are selected from a group consisting of sympathetic nerves; which include the thoracic cardiac nerves, which also include intercostal nerves;

providing operating power to the stimulator; using an external appliance to transmit stimulation parameters to the stimulator; receiving the stimulation parameters at the stimulator; and generating stimulation pulses in accordance with the stimulation parameters, which pulses are generated by the stimulator (see col. 13, ln. 50 - col. 14, ln. 5, Zabara). The disclosed method of using the stimulus generator is considered to anticipate the claimed method of providing operating power because both provide stimulation signal parameters to designate the frequency with which a stimulation signal is applied to the electrode;

delivering stimulation pulses via the stimulator and the at least one electrode to the at least one of the intercostal nerves and intercostal nerve branches influencing angina pectoris as a treatment for angina pectoris (see col. 12, ln. 50-65, Zabara). The disclosed method of delivering stimulation pulses is considered to anticipate the claimed delivery because both deliver electrical stimulation to the nerves via a minimally invasive surgical procedure.

Referring to claim 21, Zabara is considered to disclose a method wherein said at least one aspect of a patient's condition is any of bloody oxygen level, electrical activity of the patient's heart, patient activity level, respiratory rate, medication level, neurotransmitter level, hormone level, interleukin level, cytokine level, lymphokine level, chemokine level, growth factor level and enzyme level (see col. 6, ln. 54- 65, Zabara). The disclosed teaches the study of pain at the neurophysiological level where pain is based on neurotransmitters.

With reference to claim 28, Zabara is considered to disclose:

Alleviating symptoms of said angina pectoris using said stimulator that applies electrical stimulation to any of an intercostal nerve, intercostal nerve branch, afferent fibers along cardiac sympathetic nerves, first through fourth thoracic sympathetic ganglia, stellate ganglia, afferent fibers along cardiac parasympathetic nerve fibers, superior cervical (vagal) cardiac nerve, interior cervical (vagal) cardiac nerve, thoracic cardiac branch of a patient's vagus nerve, parasympathetic ganglia or neurons lying in fat pads located next to a patient's sinoatrial node, atrioventricular node or ventricles, a sympathetic trunk at spinal levels T1 through T4, and sympathetic nerves in a patient's thorax, abdomen or pelvis (see col. 3, ln. 40-65, Zabara).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dana D. Greene whose telephone number is (571) 272-7138. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair>-

direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Dana D. Greene



George Manuel
Primary Examiner